MEDICAL POLICY

Excellus
An independent licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY DETAILS	
Medical Policy Title	**Varicose Vein Treatments**
Policy Number	**7.01.47**
Category	**Technology Assessment**
Original Effective Date	**04/19/01**
Committee Approval Date	**04/17/02, 12/19/02, 07/17/03, 03/18/04, 05/19/04, 04/21/05, 04/20/06, 04/19/07, 03/20/08, 09/17/09, 10/28/10, 05/19/11, 05/24/12, 06/20/13, 05/22/14, 06/18/15, 05/25/16, 05/18/17, 03/15/18, 03/21/19, 08/15/19, 08/20/20, 08/19/21, 08/18/22, 10/19/23**
Current Effective Date	**02/15/24**
Deleted Date	**N/A**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

**Note: This policy only addresses treatment of the veins of the lower extremity (e.g., great and small saphenous veins, tributary veins, and lower extremity perforator veins). This policy does not address vein stripping and ligation, please refer to the nationally recognized InterQual standards regarding vein stripping and ligation. Please refer to the policies listed below for additional resources.*

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, endovenous thermal ablation (radiofrequency or laser), microfoam sclerotherapy (e.g., Varithena/polidocanol) and cyanoacrylate adhesive (e.g., VenaSeal closure system) have been medically proven to be effective and, therefore, is considered **medically appropriate** treatment of symptomatic varicose veins (great, small, or accessory saphenous veins)/venous insufficiency when **ALL** of the following are met:
   A. Saphenous incompetence/reflux of at least 500 milliseconds (ms) is documented on duplex ultrasound; and
   B. CEAP [clinical, etiology, anatomy, pathophysiology] class C2 or greater (see Policy Guidelines); and
   C. Documentation of **ONE** or more of the following indications:
      1. Ulceration secondary to venous stasis; or
      2. Recurrent superficial thrombophlebitis; or
      3. Hemorrhage or recurrent bleeding episodes from a ruptured superficial varicosity; or
      4. Persistent pain, swelling, itching, burning, or other symptoms are associated with saphenous reflux, along with **BOTH** of the following:
         a. Symptoms significantly interfere with activities of daily living (ADLs), and
         b. Conservative management with compression therapy (e.g., hosiery or stockings) and activity modification (e.g., elevating legs, exercise, weight loss), for at least 3-months, has not improved symptoms.

II. Based on our criteria and assessment of the peer-reviewed literature, the following treatments have been medically proven to be effective and, therefore, are considered **medically necessary** as a component of the treatment of

symptomatic varicose tributaries when performed either at the same time or following prior treatment (surgical, radiofrequency, or laser) of the saphenous veins:

A. Phlebectomy (also known as ambulatory phlebectomy, hook phlebectomy, microphlebectomy, miniphlebectomy, stab avulsion);
B. Sclerotherapy;
C. Transilluminated powered phlebectomy (TPP/TIPP, TriVex).

III. Based upon our criteria and assessment of the peer-reviewed literature, the following treatments do not improve patient outcomes and, therefore, are considered **not medically necessary**:

A. Compressive sclerotherapy, when performed for dermal or subdermal cosmetic lesions, star and/or flare lesions, spider nevi, and/or telangiectasia;
B. Microsclerosis (injection of telangiectasia or spider veins);
C. Non-compressive sclerotherapy;
D. Transcutaneous laser ablation of telangiectasia; and
E. Any treatment technique for asymptomatic varicose veins.

IV. Based upon our criteria and assessment of the peer-reviewed literature, the following treatments have not been medically proven to be effective and, therefore, are considered **investigational**:

A. Intense pulsed light source (photothermal sclerosis) for the treatment of superficial veins;
B. Mechanochemical endovenous ablation (MOCA) (e.g., ClariVein) of any vein (36473, 36474**)**;
C. Coil embolization;
D. Sclerotherapy of isolated tributary veins without prior or concurrent treatment of saphenous veins;
E. Sclerotherapy of perforator veins;
F. Sclerotherapy of the great saphenous vein, with or without associated ligation of the saphenofemoral junction;
G. Catheter-assisted sclerotherapy (e.g., KAVS catheter) (CPT 0542T);
H. Endovenous ablation (radiofrequency or laser) of tributary veins;
I. Transcutaneous laser ablation of small diameter veins; and
J. Cryostripping (cryoablation cryotherapy, or cryosurgery) of any vein.

Refer to Corporate Medical Policy #4.01.10 Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion Syndrome

Refer to Corporate Medical Policy #7.01.11 Cosmetic and Reconstructive Procedures, for treatment of telangiectasia

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINE

I. The CEAP (clinical, etiologic, anatomic, pathophysiologic) classification system is an internationally accepted standard for describing patients with chronic venous disorders (Lurie, 2020):

C class	Description
C – Clinical Classification	C0: No visible or palpable signs of venous disease
	C1: Telangiectasias or reticular veins
	C2: Varicose veins
	C2r: Recurrent varicose veins
	C3: Edema
	C4: Changes in skin and subcutaneous tissue secondary to CVD
	C4a: Pigmentation or eczema
	C4b: Lipodermatosclerosis or atrophie blanche
	C4c: Corona phlebectatica

	C5: Healed
	C6: Active venous ulcer
	C6r: Recurrent active venous ulcer
	Cs: Symptomatic
	Ca: Asymptomatic
E - Etiology	Ep: Primary
	Es: Secondary
	Esi: Secondary intravenous
	Ese: Secondary extravenous
	Ec: Congenital
	En: No cause identified
A - Anatomy	As: Superficial veins
	Ap: Perforator veins
	Ad: Deep veins
	An: No venous location identified
P - Pathophysiology	Pr: Reflux
	Po: Obstruction
	Pr.o: Reflux and obstruction
	Pn: No venous pathophysiology identified

DESCRIPTION

The venous system of the lower extremities consists of the superficial veins (this includes the great and small saphenous and accessory, or duplicate, veins that travel in parallel with the great and small saphenous veins), the deep system (popliteal and femoral veins), and perforator veins that cross through the fascia and connect the deep and superficial systems. One-way valves are present within all veins to direct the return of blood up the lower limb. Because the venous pressure in the deep system is generally greater than that of the superficial system, valve incompetence at any level may lead to backflow (venous reflux) with pooling of blood in superficial veins.

Varicose veins are dilated, elongated, tortuous, subcutaneous veins three (3) millimeters or greater in diameter. They may involve the saphenous veins (great or small), saphenous tributaries, or nonsaphenous superficial leg veins. These visible varicosities may be the only sign of venous reflux, although itching, heaviness, tension, aching, and pain may also occur. Chronic venous insufficiency secondary to venous reflux can lead to thrombophlebitis, leg ulcerations, and hemorrhage. The CEAP classification of venous disease considers the clinical, etiologic, anatomic, and pathologic characteristics of venous insufficiency, ranging from class 0 (no visible sign of disease) to class 6 (active ulceration).

The term “varicose veins” does not apply to telangiectatic dermal veins, which may be described as spider veins or broken blood vessels. While abnormal in appearance, these veins typically are not associated with any symptoms (such as pain or heaviness), and their treatment is typically considered cosmetic in nature.

A variety of treatment modalities are available to treat varicose veins/venous insufficiency, including surgery, thermal ablation, sclerotherapy, mechanochemical ablation (MOCA), cyanoacrylate adhesive (CAC), and cryotherapy. The application of each modality is influenced by the severity of the symptoms, type of vein, source of venous reflux, and the use of other (prior or concurrent) treatment. Treatment options typically focus, first, on identifying and correcting the site of reflux, and second, on redirecting venous flow through veins with intact valves.

Endovenous-Radiofrequency Ablation (RFA)

A minimally invasive alternative to vein ligation and stripping. The technique relies on radiofrequency energy to damage the intimal wall of the vessel, resulting in fibrosis and, ultimately, obliteration of a long segment of the vein, thus eliminating reflux. The procedure is performed by means of a specifically designed catheter (VNUS ClosureFAST catheter, VNUS Technologies) inserted through a small incision in the distal medial thigh to within 1-2 cm of the sapheno-femoral junction. High frequency radiowaves (200-300 kHz) are delivered through the catheter electrode, causing direct heating of the adjacent tissues. The vein is heated to approximately 120^{o} C for 20-second intervals, to sequentially heat and ablate the vein in 7 cm increments.

Endovenous Laser Ablation

A minimally invasive alternative to vein ligation and stripping, performed similarly to RFA, for symptomatic varicose veins (i.e., endovenous laser ablation [EVLA] and endovenous laser treatment [EVLT]). It is performed by introducing a bare-tipped or ceramic-coated tip laser fiber through a small incision into the greater saphenous vein under ultrasound guidance. The laser is activated, and the resulting heat at the tip causes a reaction in the walls of the vein. Then, the tip fiber is slowly removed along the course of the saphenous vein. Damage to the intimal wall of the vessel results in fibrosis and, ultimately, obliteration of a long segment of the vein. The varicosities associated with this vein then disappear, and blood from the lower leg reroutes through deeper circulation.

In transcutaneous laser ablation of small diameter veins, a small spot of laser travels through the skin and is absorbed by the blood within the vein. The resulting heat coagulates the blood and destroys the function of the vein. Over time the vein will be absorbed by the body and will disappear.

Sclerotherapy (Sclerosing Injection/Compression Therapy)

Sclerotherapy is a method of eliminating cutaneous varicose veins in which a sclerosing agent is injected into the veins. The principle of sclerotherapy is to cause irreversible endothelial injury in the desired location, while avoiding any damage to normal vessels that may be interconnected with the abnormal vessel being treated. Sclerotherapy usually requires no anesthesia and is performed in the outpatient setting or in the practitioner's office setting. It is sometimes performed in situations that might otherwise require surgery. As the saphenous vein is not visible with the naked eye, injection may be guided by ultrasonography; the combined procedure is sometimes referred to as echosclerotherapy.

Technical improvements in sclerotherapy have included the routine use of Duplex ultrasound to target refluxing vessels, luminal compression of the vein with anesthetics, and a foam/sclerosant injectate in place of liquid sclerosant. Foam sclerosants are produced by forcibly mixing a gas (e.g., air or carbon dioxide) with a liquid sclerosant (e.g., polidocanol or sodium tetradecyl sulfate). In November 2013, the FDA approved Varithena, a foam sclerosant that utilizes micro-bubbles (microfoam) and is composed of polidocanol. Varithena is dispensed from a canister with a controlled density and a more consistent bubble size. Varithena is used for the treatment of incompetent great saphenous veins, accessory saphenous veins, and visible varicosities of the great saphenous vein system above and below the knee.

Compressive sclerotherapy involves injection of the sclerosant into an "empty" vein (elevated limb) followed by application of compressive dressings. This is the most commonly performed sclerotherapy procedure for varicose veins of the lower extremities.

Catheter-assisted vein sclerotherapy (KAVS catheter) uses an intravascular double-lumen catheter with a balloon at the distal end to temporarily block blood flow to the segment of the vein being targeted for sclerotherapy. In theory, the procedure would improve sclerotherapy by avoiding drainage of the sclerosant foam and allowing for more control of the contract duration between the vessel wall and sclerosant foam (Brodersen et al., 2007).

Cyanoacrylate Adhesive

Cyanoacrylate adhesive is a clear, free-flowing liquid that polymerizes in the vessel via an anionic mechanism (i.e., polymerizes into a solid material on contact with body fluids or tissue). Once the adhesive is injected, the area is manually compressed. and the adhesive changes into a solid. to seal the varicose vein. Cyanoacrylate glue has been used as a surgical adhesive and sealant for a variety of indications, including gastrointestinal bleeding, embolization of brain arteriovenous malformations, and surgical incisions or other skin wounds.

Ambulatory Phlebectomy

Ambulatory phlebectomy (also known as microphlebectomy or microincisional phlebectomy) is the removal of varicose veins through a series of tiny incisions along the path of an enlarged vein. Prior to surgery, the degree of reflux in incompetent veins is evaluated, and the location of the veins is determined by Doppler ultrasound. The vessels are marked with a surgical marker. The surgical procedure is done under local tumescent anesthesia. Small pinhole incisions are made adjacent to the varicose veins. A small stripper head is inserted and used to turn the vein inside out and peel it away from the soft tissues of the leg through a minimal skin opening. Afterward, the leg is wrapped with a compression bandage.

Stab phlebectomy (also known as "crochet hook" stab avulsion) is another type of ambulatory phlebectomy.

Transilluminated powered phlebectomy (TPP/TIPP), also known as the TriVex procedure, is a minimally invasive type of ambulatory phlebectomy offered as an alternative to standard surgery for symptomatic varicosities of the leg. It is a three-part procedure performed under general, regional, or local anesthesia. It begins with tumescent anesthesia, to enhance visualization surrounding the varicose veins and to reduce operative discomfort. Tumescence anesthesia involves infusion of large amounts of saline mixed with lidocaine, to reduce hemorrhage, and epinephrine, to delay absorption of lidocaine. Once adequate tumescent infiltration is achieved, the resector and illuminator are inserted and positioned underneath the skin through small (2-3 cm) incisions on either end of the varicosity. The tip of the resector follows the veins slowly, to chop the veins and aspirate fragments. Once removal of the affected vein(s) is complete, a second stage tumescent anesthesia is employed, to minimize blood loss, reduce bruising and hematoma formation, and decrease post-operative pain. The incisions are then closed using surgical tape or similar closures, and the leg is wrapped.

Intense Pulsed Light Source

Intense pulsed light source or photothermal sclerosis (such as PhotoDerm Vasculite). The light source used for this procedure is not a laser and involves no needles or incisions. Treatment consists of small pulses of light energy traveling through the skin, which is absorbed by the blood, changed to heat, destroying the vein. It is used for smaller surface veins.

Mechanochemical Endovenous Ablation (MOCA)

MOCA utilizes both sclerotherapy and mechanical damage to the lumen. Following ultrasound imaging, a disposable catheter with a motor drive is inserted into the distal end of the target vein and advanced to the saphenofemoral junction. As the catheter is pulled back, a wire rotates within the lumen of the vein, abrading the lumen. At the same time, a liquid sclerosant (sodium tetradecyl sulphate) is infused near the rotating wire. It is proposed that mechanical ablation allows for better efficacy of the sclerosant, without the need for the tumescent anesthesia used in RFA or EVLA.

The ClariVein Infusion Catheter, which is utilized to perform MOCA, received Section 510(k) approval from the FDA in February 2008. The system includes an infusion catheter, motor drive, stopcock, and syringe. It is intended for the infusion of physician-specified agents into the peripheral vasculature.

Other Treatments

Other proposed methods of treating varicose veins include steam injection (Steam Vein Sclerosis System [SVS, VenoSteam], CermaVEIN, France) and endovenous microwave ablation (Microwave Intracavitary Coagulation System, Shanghai Medical Electronics, China). Results of a small, preliminary study performed outside of the U.S., have been reported for each system. Neither of these procedures has been approved or cleared for marketing by the FDA. A search of the FDA website did not identify any information regarding either system.

Cryostripping (cryoablation)

The principle of cryostripping consists of venous catheterization with a special probe that is cooled, causing it to adhere well to the vein, thus enabling its removal (Matei et al., 2022). Cryostripping uses extreme cold to cause injury to the vessel and has been suggested as an alternative approach to traditional ligation and stripping.

RATIONALE

Endovenous Thermal Ablation (Radiofrequency [RFA] and Laser [EVAS/EVLT])

In 1999, the VNUS Closure System was approved by the FDA for endovascular coagulation of blood vessels in patients with superficial vein reflux. Clinical evidence supports the safety and efficacy of endovenous RFA (e.g., VNUS) of the greater saphenous vein, as an alternative to saphenous vein ligation and stripping, in patients with documented symptomatic saphenofemoral reflux. Although the studies have a short follow-up period, in one study of 301 limbs, 89% of procedures were successful after five months, with no evidence of recannulation. In a randomized, controlled clinical trial of 28 patients, all cases were considered successful after a 50-day follow-up, based on the absence of Duplex-detected flow in the treated segments of the greater saphenous veins. In a clinical trial of 26 limbs in 26 patients, the long saphenous vein was successfully occluded in 88% of patients. These studies suggest that endoluminal RFA of the greater saphenous vein is effective as a treatment option for symptomatic varicose veins and is associated with faster post-operative recovery and less pain.

In 2002, the Diomed 810 nm surgical laser and EVLT procedure kit received FDA clearance for use in the endovascular coagulation of the greater saphenous vein of the thigh, in patients with superficial vein reflux. There is little clinical evidence in the form of randomized, prospective clinical trials, to support endovenous laser ablation of the greater saphenous vein (ELAS, EVLT) or transcutaneous laser ablation of small diameter veins. Available studies are small, with short-term follow-up. However, available studies support the safety and efficacy of ELAS and EVLT in patients with documented symptomatic saphenofemoral reflux.

The American College of Phlebology (ACP) published revised practice guidelines for the treatment of superficial venous disease of the lower leg (ACP, 2014, rev 02/03/16). ACP recommended endovenous thermal ablation (laser and radiofrequency) as the preferred treatment for saphenous and accessory saphenous vein incompetence (Grade 1B: strong recommendation, moderate quality of evidence).

Sclerotherapy

Various sclerosants (e.g., sodium tetradecyl sulfate and sodium sulfate) have been approved by the FDA for the treatment of varicose veins of the lower extremity. Published clinical trials support the safety and efficacy of conventional sclerotherapy for lower extremity varicose veins.

Compressive sclerotherapy has been found to be as effective as surgery in relieving the symptoms associated with varicose veins, with few complications. Studies consider sclerotherapy successful based on the absence of Duplex-detected flow in the treated segments of the greater saphenous veins, and sclerotherapy is associated with a faster post-operative recovery.

Clinical evidence indicates that sclerotherapy of varicose tributaries alone is less effective than treatment that includes control of the underlying refluxing veins. However, as recurrence typically arises after two to four years, isolated sclerotherapy may be medically appropriate for patients in whom long-term control of venous reflux is not a treatment goal (for example, older patients who experience recurrent bleeding from varicose blebs or who have recurrent thrombophlebitis in varicose tributaries).

Sclerotherapy of the greater saphenous vein raises issues regarding appropriate volume and concentration of the sclerosant and the ability to provide adequate post-procedure compression, as the greater saphenous vein is larger and deeper than telangiectatic dermal veins. Also, the use of sclerotherapy, as opposed to the physical removal of the vein with stripping, raises the issue of recurrence due to recanalization.

Non-compressive sclerotherapy has not been shown to be effective in producing long-term obliteration of the incompetent veins.

In 2005, the FDA granted pre-market approval to the KAVS Catheter to temporarily inhibit blood flow in isolated section of peripheral veins in order to inject physician prescribed medications. Evidence evaluating the safety and efficacy of KAVS sclerotherapy is lacking published peer-reviewed scientific literature.

Cyanoacrylate Adhesive

On Feb 20, 2015, the FDA granted pre-market approval to the VenaSeal Closure System, to treat superficial varicosities of the legs through endovascular embolization. It is intended for adults with clinically symptomatic venous reflux that has been diagnosed by Duplex ultrasound. The VenaSeal Closure System is a tumescentless technique that utilizes a

cyanoacrylate-based adhesive, which is injected into a diseased vein via a catheter inserted through the skin, while being monitored by ultrasound.

The VenaSeal pivotal study (VeClose), a multi-center, non-inferiority trial with 222 patients, compared CAE (n = 108), the VenaSeal Sapheon Closure System with RFA (n = 114), and the ClosureFast system, for the treatment of symptomatic, incompetent great saphenous veins. After discharge, subjects returned to the clinic on day 3 and again at months 1 and 3. The study's primary endpoint was closure of the target vein at month 3, as assessed by Duplex ultrasound and adjudicated by an independent vascular ultrasound core laboratory. Statistical testing focused on showing non-inferiority with a 10% delta conditionally followed by superiority testing. No adjunctive procedures were allowed until after the month 3 visit, and missing month 3 data were imputed by various methods. Secondary end points included patient-reported pain during vein treatment and extent of ecchymosis at day 3. Additional assessments included general and disease-specific quality of life surveys and adverse event rates. The primary end point (the proportion of patients with complete closure of the target great saphenous vein at 3 months measured by ultrasound) was noninferior to RFA, with a 99% closure rate for VenaSeal compared with 96% for RFA. All primary end point analyses, which used various methods to account for the missing data rate (14%), showed evidence to support the study's non-inferiority hypothesis (all $P < .01$); some of the analyses supported a trend toward superiority ($P = .07$ in the predictive model). Pain experienced during the procedure was mild and similar between treatment groups (2.2 and 2.4 for CAE and RFA, respectively, on a 10-point scale; $P = .11$). The secondary end point (intraoperative pain) was similar for both groups (2.2 on a 10-point scale for VenaSeal vs 2.4 for RFA, $p=0.11$). Ecchymosis at day 3 was significantly lower in the cyanoacrylate group; 67.6% of patients treated with cyanoacrylate had no ecchymosis compared with 48.2% of patients following RFA ($p<0.01$). Scores on the Aberdeen Varicose Vein Questionnaire (AVVQ) and Venous Clinical Severity Score (VCSS) improved to a similar extent in the 2 groups. Other adverse events occurred at a similar rate between groups and were generally mild and well tolerated. The authors concluded that CAE was proven to be non-inferior to RFA for the treatment of incompetent great saphenous veins at month 3 after the procedure, that both treatment methods showed good safety profiles, and that CAE does not require tumescent anesthesia and is associated with less post-procedure ecchymosis. (Morrison et al, 2015).

Morrison, N. et al. reported on the 36-month outcomes of the VeClose trial (2018), which compared treatment of incompetent great saphenous veins using cyanoacrylate closure (CAC) versus RFA. At 36 months, 146 patients completed the follow-up, 72 in the CAC group and 74 in the RFA group. The closure rates at months 3, 6, 12, and 24 were reported to be 99%, 99%, 96.8%, and 95.3%, respectively, for the CAC group. The closure rates at months 3, 6, 12, and 24 were reported to be 95.4%, 96.2%, 95.9%, and 94.0%, respectively, for the RFA group. The great saphenous vein closure rate at 36 months was 94.4% in the CAC group and 91.9% in the RFA group. The authors concluded that the trial reports similar great saphenous vein closure rates with both CAC and RFA at 36 months, further confirming the durability and non-inferiority of CAC compared to RFA.

Ambulatory Phlebectomy

Ambulatory phlebectomy, including, but not limited to, transilluminated powered phlebectomy (TPP/TIPP, TriVex) and stab phlebectomy, are variations of currently accepted surgical techniques for the treatment of varicose veins. In October 2003, the Trivex system, a device for transilluminated powered phlebectomy, was approved by the FDA. Various case series describe initial experience with transilluminated powered phlebectomy. In general, these studies demonstrate its technical feasibility and report that the technique is associated with decreased surgical time and decreased number of incisions, compared to historical controls. A randomized study of 141 patients (188 limbs) compared removal of superficial varicosities with either stab avulsions or the TriVex system. Authors concluded that the TriVex system was a safe and effective method of excision of varicosities that compared well to standard stab avulsion.

Coil Embolization

Coil embolization, also known as coil occlusion, involves the use of a coil, either alone or combined with a sclerosant, to occlude the vein. Coil embolization is under investigation for treatment of lower extremity varicose veins. The technique may involve the use of more than one coil within the great saphenous vein. Evidence in the peer-reviewed, published literature evaluating this method of treatment for lower extremity varicosities is very limited (e.g., van Dijk et al. 1999; Viani et al. 2014; and Kayssi et al. 2017). Additional clinical trials are necessary, to develop strong conclusions regarding safety and efficacy.

Mechanochemical Endovenous Ablation (MOCA)

The evidence on MOCA includes 4 RCTs that compared MOCA to thermal ablation with 6-month to 2-year results, and a prospective cohort with follow-up out to 5 years. Results to date have been mixed regarding a reduction in intraprocedural pain, which is a proposed benefit of MOCA compared to thermal ablation procedures. Occlusion rates at 6 months to 2 years in the RCTs indicate lower anatomic success rates compared to thermal ablation, but a difference in clinical outcomes at these early time points has not been observed.

Matei et al. (2022) conducted a retrospective analysis of 1,087 patients (1,182 operated limbs) with CVD who underwent cyrostripping between September 2013 to September 2021. The study group included 756 female and 331 male patients with an age range between 19 and 87 years old. The enrolled patients were in all stages of the disease in which venous reflux is encountered, as follows: 864 patients (79.48%) in C2 and C3 stages, 164 patients (15.08%) in C4 stage, 59 patients (5.42%) in C5 and C6 stages.

Mohamed et al. (2020) reported on the ongoing Randomized Clinical Trial Comparing Endovenous Laser Ablation and Mechanochemical Ablation (ClariVein) in the Management of Superficial Venous Insufficiency (LAMA). Patients (n=150) were randomized to MOCA with 1.5% sodium tetradecyl sulfate or to endovenous laser ablation. Anatomic success (occlusion) rates were lower in the MOCA group (77%) compared to the endovenous laser ablation group (91%) with no significant difference between the two treatments in intraprocedural pain scores. In contrast to the difference in anatomical occlusion rates, clinical severity and quality of life scores were not significantly different between the groups at 1 year follow-up. Follow-up is continuing to evaluate the durability of the treatments.

In 2017, Lane et al. reported on results from an RCT of 170 patients that compared ClariVein with RFA. Maximum visual analog scale (VAS) pain scores (out of 100) during the procedure were significantly lower in the MOCA group (median, 15 mm) than in the RFA group (median, 34 mm; p=0.003). Average VAS pain scores during the procedure were also significantly lower in the MOCA group (median, 10 mm) than in the RFA group (median, 19.5 mm; p=0.003). Occlusion rates, clinical severity scores, disease-specific quality of life, and generic quality of life scores were similar between the groups at one and six months. However, only 71% of patients were available for follow-up at six months, limiting the evaluation of closure rates at that time point.

Cryostripping (cryoablation)

In 2005, a modified Erbe Erbokryo cryosurgical unit (Erbe USA) was approved by the FDA for marketing through the 510(k) process. A variety of clinical indications are listed, including cryostripping of varicose veins of the lower limbs.

Evidence is limited in quality and quantity, with mixed results. For individuals who have varicose veins/venous insufficiency and saphenous vein reflux who receive cryoablation, the evidence includes RCTs. Results from a recent RCT of cryoablation have indicated that this therapy is inferior to conventional stripping. Studies showing a benefit on health outcomes are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Klem et al (2009) reported on a randomized trial that found endovenous cryoablation (n=249) to be inferior to conventional stripping (n=245) for treating patients with symptomatic varicose veins. Disselhoff et al (2011) reported on 5-year outcomes from a randomized trial that compared cryoablation with endovenous laser ablation. Included were 120 patients with symptomatic uncomplicated varicose veins (CEAP class C2) with saphenofemoral incompetence and great saphenous vein reflux. Neovascularization was more common after cryoablation, but incompetent tributaries were more common arteriovenous laser ablation. There were no significant differences between groups in the Venous Clinical Severity Score or AVVQ scores at either the 2 or 5-month follow-up for endovenous laser ablation.

The Society for Vascular Surgery and the American Venous Forum (2011) published joint clinical practice guidelines that indicated cryostripping is a technique that is new in the United States, and it has not been fully evaluated (Grade 1B).

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).*

CPT Codes

Code	Description
0524T **(E/I)**	Endovenous catheter directed chemical ablation with balloon isolation of incompetent extremity vein, open or percutaneous, including all vascular access, catheter manipulation, diagnostic imaging, imaging guidance and monitoring
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein) (e.g., Varithena)
36466	multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg (reported once per extremity, regardless of the number of VEINS treated) (e.g., Varithena)
36468 **(NMN)**	Injection(s) of sclerosant for spider veins (telangiectasia), limb or trunk
36470	Injection of sclerosing solution; single incompetent vein (other than telangiectasia)
36471	multiple incompetent veins (other than telangiectasia), same leg (reported once per extremity, regardless of the number of VEINS treated)
36473 **(E/I)**	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated (MOCA) (e.g., ClariVein)
36474 **(E/I)**	subsequent vein(s) treated in a single extremity, each through separate access sites (list separately, in addition to code, for primary procedure) (List separately in addition to code for primary procedure) (may only be reported once per extremity, regardless of the number of additional vein(s) treated)
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated (e.g., Covidien, Venefit)
36476	subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (may only be reported once per extremity, regardless of the number of additional vein(s) treated)
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure) (may only be reported once per extremity, regardless of the number of additional vein(s) treated)
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (e.g., cyanoacrylate - CAE) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated (e.g., VenaSeal)
36483	subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure and may only be reported once per extremity, regardless of the number of additional vein(s) treated) (e.g., VenaSeal)
37241 **(*E/I)**	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles) (e.g., coil embolization) (***E/I for the ICD-10-CM diagnosis codes listed below**)
37765	Stab phlebectomy of varicose veins, one extremity; 10-20 stab incisions

Code	Description
37766	Stab phlebectomy of varicose veins, one extremity; more than 20 incisions
37799	Unlisted procedure, vascular surgery **Note: Code may be used for stab phlebectomy of varicose veins; less than 10 incisions**

HCPCS Codes

Code	Description
S2202	Echosclerotherapy

ICD10 Codes

Code	Description
I83.001-I83.229	Varicose veins of lower extremities with ulcer and/or inflammation (code range)
I83.811-I83.899	Varicose veins of lower extremities with other complications (code range)
I87.2	Venous insufficiency (chronic) (peripheral)
I87.9	Disorder of vein, unspecified

REFERENCES

*American College of Phlebology. Treatment of superficial venous disease of the lower leg. Practice guidelines. 2016 Feb 03. [https://www.myavls.org/assets/pdf/SuperficialVenousDiseaseGuidelinesPMS313-02.03.16.pdf] accessed 07/11/23.

Baccellieri D, et al. Early results of mechanochemical ablation for small saphenous vein incompetency using 2% polidocanol. J Vasc Surg Venous Lymphat Disord 2021 May;9(3):683-690.

*Brodersen JP, et al. Catheter-assisted vein sclerotherapy: a new approach for sclerotherapy of the greater saphenous vein with a double-lumen balloon catheter. Dermatol Surg 2007 Apr;33(4):469-475. doi: 10.1111/j.1524-4725.2007.33095.x. PMID: 17430382.

Brittenden J, et al. Five-year outcomes of a randomized trial of treatments for varicose veins. N Engl J Med 2019 Sep 5;381(10):912-922.

*Carroll C, et al. Systematic review, network meta-analysis and exploratory cost-effectiveness model of randomized trials of minimally invasive techniques versus surgery for varicose veins. Br J Surg 2014 Aug;101(9):1040-52.

*Chan YC, et al. Predictors of Recanalization for Incompetent Great Saphenous Veins Treated with Cyanoacrylate Glue. J Vasc Interv Radiol 2017 May;28(5):665-671.

*De Maeseneer MG, et al. European Society for Vascular Surgery (ESVS) 2022 Clinical Practice Guidelines on the Management of Chronic Venous Disease of the Lower Limbs. European J Vasc and Endovasc Surg 2022;63(2):184-267.

*Disselhoff BC, et al. Five-year results of a randomized clinical trial comparing endovenous laser ablation with cryostripping for great saphenous varicose veins. Br J Surg 2011 Aug;98(8):1107-1111. PMID 21633948

*Elias S and Raines JK. Mechanochemical tumescentless endovenous ablation: final results of the initial clinical trial. Phlebology 2012;27(2):67-72.

Epstein D, et al. Cost-effectiveness of current and emerging treatments of varicose veins. Value Health 2018 Aug;21(8):911-920.

Gibson K, et al. Twenty-four month results from a randomized trial of cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venous Lymphat Disord 2018 Sep;6(5):606-613.

*Gloviczki P, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. J Vasc Surg 2011 May;53(5 Suppl):2S-48S.

*Gloviczki P, et al. The 2022 Society for Vascular Surgery, American Venous Forum, and American Vein and Lymphatic Society clinical practice guidelines for the management of varicose veins of the lower extremities. Part I. Duplex scanning and treatment of superficial truncal reflux: endorsed by the society for vascular medicine and the international union of phlebology. J Vasc Surg Venous Lymphat Disord 2023 Mar;11(2):231-261.e6. [doi: 10.1016/j.jvsv.2022.09.004]. Epub 2022 Oct 12.

Gohel MS. The ongoing search for clarity regarding the role of cyanoacrylate closure for superficial venous reflux. J Vasc Surg Venous Lymphat Disord 2020 Nov;8(6):990.

Hamann SAS, et al. Randomized clinical trial of endovenous laser ablation versus direct and indirect radiofrequency ablation for the treatment of great saphenous varicose veins. Br J Surg 2019 Jul;106(8):998-1004.

Hassanin A, et al. A systematic review and meta-analysis of comparative studies comparing nonthermal versus thermal endovenous ablation in superficial venous incompetence. J Vasc Surg Venous Lymphat Disord 2019 Nov;7(6):902-913.e3.

Holewijn S, et al. Two-year results of a multicenter randomized controlled trial comparing mechanochemical endovenous ablation to radiofrequency ablation in the treatment of primary great saphenous vein incompetence (MARADONA Trial). J Vasc Surg Venous Lymphat Disord 2019 May;7(3):364-374.

Kawai Y, et al. Endovenous laser ablation with and without concomitant phlebectomy for the treatment of varicose veins: a retrospective analysis of 954 limbs. Ann Vasc Surg 2020 Jul;66:344-350.

*Kayssi A, et al. Combined coil embolization and foam sclerotherapy for the management of varicose veins. Ann Vasc Surg 2017 Jan;38:293-297.

*Kim KY and Kim JW. Early experience of transilluminated cryosurgery for varicose vein with saphenofemoral reflux: review of 84 patients (131 limbs). Annals of Surg Treatment and Research 2017;92(2):98-102.

Kim SY, et al. Mechanochemical ablation as an alternative to venous ulcer healing compared with thermal ablation. J Vasc Surg Venous Lymphat Disord 2019 Sep;7(5):699-705.

*Klem TM, et al. A randomized trial of cryo stripping versus conventional stripping of the great saphenous vein. J Vasc Surg 2009 Feb;49(2):403-409. PMID 19028042.

Kolluri R, et al. Network meta-analysis to compare VenaSeal with other superficial venous therapies for chronic venous insufficiency. J Vasc Surg Venous Lymphat Disord 2020 May;8(3):472-481.e3.

Kolvenbach RR, et al. The V-block occlusion stent and sclerotherapy device for varicose vein treatment: a retrospective analysis. Ann Vasc Surg 2019 Aug;59:231-236.

Lam LY et al. A multicenter, randomized, dose-finding study of mechanochemical ablation using ClariVein and liquid polidocanol for great saphenous vein incompetence. Vasc Surg Venous Lymphat Disord 2022 Jul;10(4):856-64.

*Lane T, et al. A multi-centre randomised controlled trial comparing radiofrequency and mechanical occlusion chemically assisted ablation of varicose veins - Final results of the Venefit versus Clarivein for varicose veins trial. Phlebology Mar 2017;32(2):89-98

*Lane TRA, et al. Retrograde inversion stripping as a complication of the ClariVein® mechanochemical venous ablation procedure. Annals of the Royal College of Surgeons 97: e18–20 (2015)

Liu X, et al. A retrospective cohort study comparing two treatments for active venous leg ulcers. Medicine (Baltimore) 2020 Feb;99(8):e19317.

*Lurie F, et al. Compression therapy after invasive treatment of superficial veins of the lower extremities: Clinical practice guidelines of the American Venous Forum, Society for Vascular Surgery, American College of Phlebology, Society for Vascular Medicine, and International Union of Phlebology. J of Vasc Surg 2019;7(1):17-28.

*Lurie F, et al. The 2020 update of the CEAP classification system and reporting standards. J of Vas Surg 2020;8(3):342-352.

Masuda E, et al. The 2020 appropriate use criteria for chronic lower extremity venous disease of the American Venous Forum, the Society for Vascular Surgery, the American Vein and Lymphatic Society, and the Society of Interventional Radiology. J Vasc Surg Venous Lymphat Disord 2020 Jul;8(4):505-525.e4.

Matei SC, et al. Cryostripping - a safe and efficient alternative procedure in chronic venous disease treatment. J Clin Med 2022;11(17):5028.

Mohamed AH, et al. A randomized controlled trial of endovenous laser ablation versus mechanochemical ablation with ClariVein in the management of superficial venous incompetence (LAMA trial). Annals of Surg 2021 Jun;273(6):e188-95.

*Morrison N, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg 2015 Apr;61(4):985-94.

*Morrison N, et al. Comparison of cyanoacrylate embolization and radiofrequency ablation for the treatment of incompetent great saphenous veins: 36-month outcomes of VeClose randomized controlled trial. Phlebology 2018 Nov 7; 0(0)1-11.

*Morrison N, et al. Five-year extension study of patients from a randomized clinical trial (VeClose) comparing cyanoacrylate closure versus radiofrequency ablation for the treatment of incompetent great saphenous veins. J Vasc Surg Venbous Lymphat Disord 2020 Mar 20;S2213-333X(20)30105-0 [Online ahead of print].

*NICE Guidelines Endovenous mechanochemical ablation for varicose veins. Interventional procedures guidance [IPG557]. 2016 May 25 [https://www.nice.org.uk/guidance/ipg557] accessed 07/11/23.

*Sarvananthan T, et al. Neurological complications of sclerotherapy for varicose veins. J Vasc Surg 2012 Jan;55(1):243-51.

Tang TY, et al. ClariVein® - Early results from a large single-centre series of mechanochemical endovenous ablation for varicose veins. Phlebology 2017 Feb;32(1):6-12. doi: 10.1177/0268355516630154

Tang TY, et al. Early results (3 months) of an Asian prospective multi-centre VenaSeal™ real world post-market evaluation to investigate the efficacy and safety of cyanoacrylate endovenous ablation for varicose veins (ASVS Study). J Vasc Surg Venous Lymphat Disord 2020 May 6;S2213-333X(20)30238-9 [Online ahead of print].

Tawfik AM, et al. Laser ablation versus mechanochemical ablation in the treatment of primary varicose veins: a randomized clinical trial. J Vasc Surg Venous Lymphat Disord 2020 Mar;8(2):211-215.

Thierens N, et al. Five-year outcomes of mechano-chemical ablation of primary great saphenous vein incompetence. Phlebology 2020 May;35(4):255-261.

*Tisi PV, et al. Injection sclerotherapy for varicose veins. Cochrane Database Syst Rev 2006(4):CD001732.

U.S. Food and Drug Administration. Drug approval package. Varithena, (polidocanol) injectable foam. 2014 Jul 23 [https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/205098orig1s018ltr.pdf] accessed 07/26/23.

Vähäaho S, et al. Randomized clinical trial of mechanochemical and endovenous thermal ablation of great saphenous varicose veins. Br J Surg 2019 Apr;106(5):548-554.

Vähäaho S, et al. Three-year results of a randomized controlled trial comparing mechanochemical and thermal ablation in the treatment of insufficient great saphenous veins. J Vasc Surg Venous Lymphat Disord 2021 May;9(3):652-659.

*van Dijk LC, et al. Ultrasound-guided percutaneous coil embolization of incompetent perforating veins: not effective for treatment of venous ulcers and recurrent varicosities. J Vasc Interv Radiol 1999 Oct;10(9):1271-4.

*van Eekeren RR, et al. Postoperative pain and early quality of life after radiofrequency ablation and mechanochemical endovenous ablation of incompetent great saphenous veins. J Vasc Surg 2013 Feb;57(2):445-50.

*van Eekeren RR, et al. Endovenous mechanochemical ablation of great saphenous vein incompetence using the ClariVein device: a safety study. J Endovasc Ther 2011 Jun;18(3):328-34.

*Viani MP, et al. One-shot scleroembolization: a new technique for the treatment of varicose veins disease of lower extremities. Preliminary results. Phebology 2014 Dec;29(10):694-7.

*Whiteley MS, et al. Mechanochemical ablation causes endothelial and medial damage to the vein wall resulting in deeper penetration of sclerosant compared with sclerotherapy alone in extrafascial great saphenous vein using an ex vivo model. J Vasc Surg Venous Lymphat Disord 2017 May;5(3):370-377

Woo HY, et al. Outcome of ClosureFAST radiofrequency ablation for large-diameter incompetent great saphenous vein. Ann Surg Treat Res 2019 Jun;96(6):313-318.

*Key Article

KEY WORDS

Ambulatory phlebectomy, ClariVein, Endoluminal radiofrequency ablation, Endovascular embolization, Endovenous laser ablation, Endovenous microwave ablation, Mechanochemical endovenous ablation (MOCA), Microfoam sclerotherapy, Pulse light source, Sclerotherapy, Stab phlebectomy, Steam Vein Sclerosis System, SVS, Varithena, VenaSeal, VenoSteam, Transilluminated powered phlebectomy, VNUS.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, the treatment of varicose veins is not addressed in a National Medicare coverage determination or policies.

There is currently a Local Coverage Determination (LCD) and two (2) supplement articles for the treatment of varicose veins of the lower extremity. Please refer to the following LCD websites for Medicare Members:

LCD (L33575) Varicose Veins of the Lower Extremity, Treatment of:

[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33575&ver=43&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=varicose+veins&KeyWordLookUp=Title&KeyWordSearchType=And&FriendlyError=NoLCDIDVersion&bc=gAAAABAAgAAA&=] accessed 07/12/23.

Article (A52870), Billing and Coding

[https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52870&ver=31] accessed 07/12/23.

Article (A55704), Response to Comments

[https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55704&ver=7] accessed 07/12/23.